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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,052	04/05/1999	SHUJI SAITOH	981167	1182
23850	7590	10/19/2005	EXAMINER	
ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP 1725 K STREET, NW SUITE 1000 WASHINGTON, DC 20006			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/147,052

Applicant(s)

SAITOH ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25,26,32,33,39-41 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) 45-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25,26,32,33,39-41 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 4, 2005 has been entered.

#### ***Amendment Entry***

2. The amendment filed August 4, 2005 has been entered. Claims 25-26 and 32-33 have been amended. Claims 1-24, 27-31, 34-38 and 42-43 have been cancelled. Claims 45-46 have been withdrawn. Claims 25-26, 32-33, 39-41 and 43-44 are under consideration in this office action.

#### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on August 4, 2005 was filed after the mailing date of the office action on May 9, 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement was considered by the examiner.

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***Withdrawal of Rejections***

4. The rejection of claims 25-26, 32-33, 39-41 and 43-44 under 35 U.S.C. 103(a) as being unpatentable over Saito et al., (WO 94/23019) and Yoshida et al., (Virology 1994 Vol. 200) and further in view of Nazerian et al. (EP 520,753) has been withdrawn in view of applicants' amendments and arguments.

***New Grounds of Objection***

***Claim Objections***

5. Claims 25-26 and 32-33 are objected to because of the following informalities: The claims refer to "herpes virus" instead of "Herpes virus." Appropriate correction is required.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 25-26, 32-33, 39-41 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a recombinant Avipox virus having DNA coding for a fusion protein, comprising: (i) an antigenic protein isolated from *Mycoplasma gallisepticum* that causes an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum, and (ii) a signal polypeptide of Herpes virus glycoproteinB protein, said signal polypeptide being ligated with said antigenic protein isolated from *Mycoplasma gallisepticum* at the N terminus thereof and there being no existence of a membrane anchor peptide such that said antigenic protein is secreted extracellularly, and wherein upon expression of said fusion protein in a host cell, said antigenic protein is secreted extracellularly.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.'" *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.*, the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ('In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .'). *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must

describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representatives, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In *Gostelli*, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a DNA encoding an antigenic protein isolated from *Mycoplasma gallisepticum* and a signal polypeptide of Herpes virus glycoproteinB protein. The generic statements drawn to the encoding DNA, the antigenic protein isolated from *Mycoplasma gallisepticum* and the signal polypeptide of Herpes virus glycoproteinB protein do not provide ample written description for fusion protein since the claims do not describe structural features. Furthermore, the statements regarding the encoding DNA and the antigenic protein being isolated from *Mycoplasma gallisepticum* which cause an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum do not sufficiently provide ample written description since this only describes the function of the DNA and antigenic protein. The specification does provide examples of what qualify as a recombinant Avipox virus having DNA coding for a fusion protein. However, these are limited to SEQ ID NO:1 and 3.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claims 25-26 and 32-33 are broad generic claims with respect all possible antigenic proteins encompassed by the claims. The possible structural variations are limitless to any class of polymer with any biomolecule. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional

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characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient as a characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163.

Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the protein beyond disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide more than two examples. The specification is limited to the above mentioned sequences, SEQ ID NO: 1 and 3. There is no disclosure of a generic recombinant Avipox virus having DNA coding for a fusion protein, comprising: (i) an antigenic protein isolated from *Mycoplasma gallisepticum* that causes an antibody-antigen reaction with *Mycoplasma gallisepticum* infected serum, and (ii) a signal polypeptide of Herpes virus glycoproteinB protein, said signal polypeptide being ligated with said antigenic protein isolated from *Mycoplasma gallisepticum* at the N terminus thereof and there being no existence of a membrane anchor peptide such that said antigenic protein is secreted extracellularly, and wherein upon expression of said fusion protein in a host cell, said antigenic protein is secreted extracellularly.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully

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ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

7. Claims 25-26, 32-33, 39-41 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 25-26 and 32-33 refer to "A recombinant Avipox virus having a DNA coding..." It is presumed that applicant intends on having more than a single deoxyribonucleic acid. Therefore it is suggested that the claim language is to not use the article "a." Suggested claim language is "A recombinant Avipox virus having DNA coding."

8. Dependant claims 39-41 and 44 refer to "A recombinant Avipox virus", however the suggested claim language is to use of the article "the." Therefore the suggested claim language is "The recombinant Avipox virus."

### ***Conclusion***

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines  
October 12, 2005

